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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,976	11/20/2003	Syed F.A. Hossainy	50623.317	2726

7590 02/18/2010
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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02/18/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/718,976	Applicant(s) HOSSAINY ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-8,13,14,16-21,23-26,31,32 and 34-40 is/are pending in the application.
- 4a) Of the above claim(s) 13,14,31,32 and 37-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8,16-21, 23-26 and 34-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Previously claims 13-14 and 31-32 were withdrawn for pertaining to an unelected species, see office action filed 03/26/2007.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3,5-8,13-14,16-21, 23-26,31-32 and 34-36, drawn to a medical device comprising a carboxylated poly(lactic acid), classified in class 424, subclass 78.17.
- II. Claims 37-40, drawn to a medical article comprising poly(lactic acid), classified in class 424, subclass 426.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related medical articles. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design in that the poly(lactide) of invention I must be carboxylated by glycolic acid, wherein invention II requires no such carboxylation. The examiner notes that there would be a search burden because poly(lactides) as claimed in invention II are very well known to be used in drug eluting medical articles such as stents, but carboxylated poly(lactic acid) by glycolic acid is not very well known as evidenced by the fact that the examiner has found no anticipatory

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rejections for invention I as now claimed. Therefore these claims sets are clearly diverging in subject matter in which the scope of one claim set is outside the scope of the other claim set and would require a separate search for both. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement

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may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Qun Liu a provisional election was made with traverse to prosecute the invention of I, claims 1-3,5-8,16-21, 23-26 and 34-36. Affirmation of this election must be made by applicant in replying to this Office action.

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Claims 37-40 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

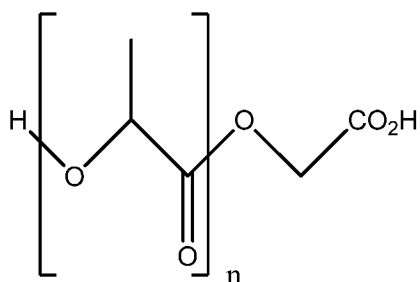
The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3,5-8,16-21, 23-26 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (US 6,258,121 B1, cited previously) in view of the teachings of Kim et al. (US 5,548,035, cited previously), incorporated by reference, Ovitt et al. J. Am Chem. Soc., 1999, 121 (16), cited previously 4072-4073 and Odian, Principles of Polymerization, 3rd edition, John Wiley and Sons, INC, pages 569-572, cited previously.

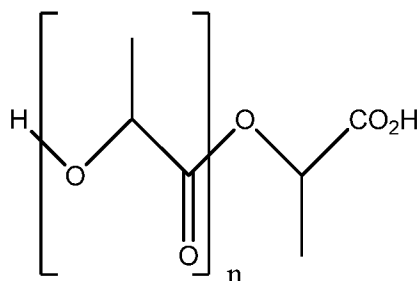
Yang discloses a stent having a polymeric coating for controllably releasing an included active agent, the coating comprises polymeric materials and blends thereof selected from polymers such as polylactide (PLA), polycaprolactone (PCL), polyhydroxybutyrate (PHB), poly(lactide-co-glycolide) (PLGA) and preferably PLA-PEO copolymer. See abstract, col 4 lin 4-22. Regarding the limitation within the claims on the structure of the carboxylated PLA, the examiner notes that the only difference between

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applicants claimed carboxylated PLA and the prior arts PLA is the glycolic acid end terminus as shown below.

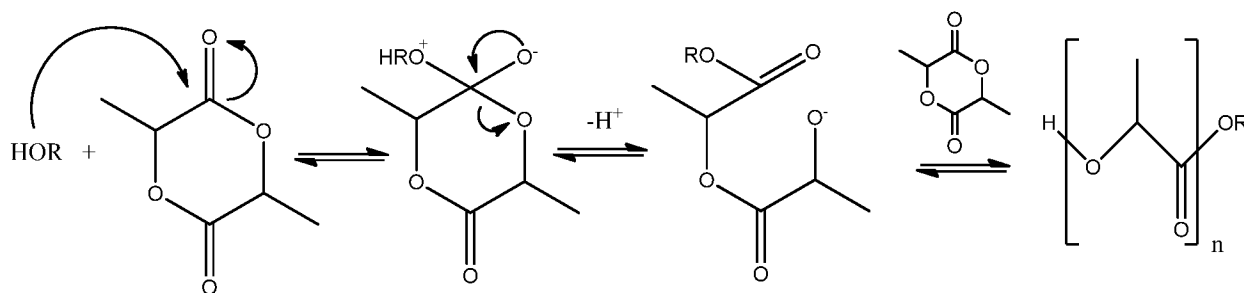
Scheme 1

Claimed



PLA as disclosed by Yang

Thus the only difference between the two structures above is a methyl group present on the end terminus of PLA verses applicants claimed invention which does not have a methyl group but hydrogen. As disclosed in the previous office action filed 02/03/2009 it is well known in the art that a nucleophilic catalyst such as a hydroxyl group will react with lactide via a ring opening process as shown in the scheme below.

Scheme 2

The examiners position is well known and supported within the art, some of the numerous teachings on lactide ring openings are found within the references cited. Ovitt

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et al. J. Am Chem. Soc., 1999, 121 (16), 4072-4073 and Odian, Principles of Polymerization, 3rd edition, John Wiley and Sons, INC, pages 569-572. Compounds containing hydroxyl groups can come from a variety of sources including hydroxy acids such as glycolic acid, therefore it would be obvious to one of ordinary skill in the art that the above reaction could take place by using glycolic acid (Substitute R in the above equation with $-\text{CH}_2\text{-CO}_2\text{H}$). Thus applicants claimed invention would have been prima facie obvious to one of ordinary skill in the art at the time of applicants claimed invention since it would be obvious that compounds such as glycolic acid could be used as a catalyst in ring opening type of polymerizations. One of ordinary skill in the art would have a high expectation of success in using glycolic acid as a ring opening catalyst to open a lactide ring since its reactivity could be predicted based upon what was already well known in the prior art. As noted above the only difference from the prior art and applicants claimed invention is the substitution of a hydrogen group for a methyl on the end terminus of PLA. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). Regarding the limitation that the PLA-PEO copolymer is a triblock, Yang incorporates by reference the PLA-PEO copolymers of Kim et al (US 5,548,035) who teaches the use of PLA-PEO-PLA blocks. See col 5 lin 5-7.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618